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EXAMINER	
YEAGER, RAYMOND P	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,376	HAM, ZORAN	
	Examiner	Art Unit	
	RAYMOND P. YEAGER	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9 and 10* is/are pending in the application.

4a) Of the above claim(s) *6,7, 9, and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/26/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 to 7 and 9 to 10 are pending.

Election/Restriction

Applicant's election with traverse of group I, claims 1 to 5 in the reply filed on 06/05/2009 is acknowledged. The traversal is on the ground(s) that Miyazawa et al, 2001 in view of US Patent 6,395,300 does not show the instant claims lack an inventive step. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant's arguments are not persuasive since the '300 reference teaches a method of enhanced dissolution of therapeutic agents wherein the method of processing (i.e. lyophilization, spray drying) ('300, column 12, lines 18-41) is the same method of preparation as recited in the instant application (instant application, page 4, paragraph 2). The applicant also asserts one of ordinary skill in the art would have to pick and choose tamsulosin hydrochloride from a long list of therapeutic agents ('300, column 7, line 45 to column 8, line 9). The '300 patent provides a process by which a number of therapeutic agents can be processed to improve dissolution, so any of the preferred drugs listed can be used in the process and are considered equivalent for the purposes of this process. MPEP § 2141 states, "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusatory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at ___, 82 USPQ2d at

1396. Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) " Obvious to try " - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention." Based on the teachings of the MPEP and KSR above, by employing the rationale in (C) above, it would be obvious for one of ordinary skill in the art to use a process of improving dissolution on any of the preferred drugs, including tamsulosin hydrochloride, as this process provides a method to overcome a rate-limiting step to attain therapeutically effective drug doses (column 1, lines 17-19). The success in processing these therapeutic agents provides one of ordinary skill with a reasonable expectation for success. Also, the number of "identified, predictable solutions" would be any preferred drug which would all be "obvious to try" in the method claimed in the instant application. Thus, it would have been *prima facie* obvious at the time the invention was made for one of ordinary skill in the art to use a process to improve the dissolution of a preferred drug ('300, column 7, line 45 to column 8, line 9).

Further, Miyazawa et al, 2001 directs one of ordinary skill in the art to the therapeutic use of tamsulosin hydrochloride in the '300 patent and the '300 patent provides a method to overcome a rate-limiting step to attain therapeutically effective drug doses ('300, column 1, lines 17-19). When the '300 application recites "a crystalline state, an amorphous state, or a mixture thereof, depending on certain factors" these options are recited in the alternative, as such processes are known to one

of ordinary skill in the art. The applicant also argues no motivation to combine was provided but applicant is directed to the 05/05/2009 restriction requirement, page 4, paragraph 1). The applicant also argues there is no search burden but search burden is not criteria for restriction but rather PCT rule 13.2 defines the criteria for restriction in a US National Stage entry per 35 USC 371.

Applicant further states that using prior art to separate groups is improper. Note that CFR 1.475(a) and PCT Rule 13.2 provides: "Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." Further, CFR 1.476(d) notes: "Lack of unity of invention may be directly evident before considering the claims in relation to any prior art, or after taking the prior art into consideration, as where a document discovered during the search shows the invention claimed in a generic or linking claim lacks novelty or is clearly obvious, leaving two or more claims joined thereby without a common inventive concept. In such a case the International Searching Authority may raise the objection of lack of unity of invention." Thus the instant claims are compared to the prior art to determine their contribution over the prior art to determine unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6, 7, 9, and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/05/2009. Thus claims 1 to 5 are examined.

Priority

Application 10/587,376 (07/26/2006) is a national stage entry of PCT/EP2005/000875 (01/28/2005) per 35 USC 371 and claims foreign priority to

SLOVENIA P-2004400032 (01/29/2004) per 35 USC 119. Foreign priority has not been perfected as no certified translation of the foreign priority document has been filed.

Information Disclosure Statement

The Information Disclosure Statement (1) has been reviewed. Applicants are reminded of their duty to disclose all information known to them to be material to patentability as defined in 37 CFR 1.56.

Objections –Claims

Claims 2 to 5 are objected to because of the following informalities: Claim 2 recites the limitation "the *DSC thermogram*" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 3 recites the limitation "the *IR spectrum*" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 4 recites the limitation "the *IR spectrum*" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 5 recites the limitation "*the X-ray powder diffractogram*" in line 2. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections – 35 USC § 112 First Paragraph – Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 to 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant claims an amorphous form of tamsulosin hydrochloride without providing a claim which is commensurate in scope

with the disclosed invention. The specification describes an amorphous form that is completely characterized by a melting point, an IR spectrum, a DSC thermogram, and the absence of x-ray diffraction peaks while the scope of the claims describes a larger genus of compounds supported in the specification because the claims only partly described these characteristics by claiming only a melting point, an IR band, or the absence of x-ray diffraction peaks.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines*, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See

MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

- *Level of skill and knowledge in the art*: MPEP 2141.03 states (in part), "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 167 LEd2d 705, 82 USPQ2d 1385, 1397 (2007). "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." Id. Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." Id. At 1396, 82 USPQ2d at 1396. The "hypothetical person having ordinary skill in the art' to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art." Ex parte Hiyamizu, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (The Board disagreed with the examiner's definition of one of ordinary skill in the art (a doctorate level engineer or scientist working at least 40 hours per week in semiconductor research or development), finding that the hypothetical person is not definable by way of credentials, and that the evidence in the application did not support

the conclusion that such a person would require a doctorate or equivalent knowledge in science or engineering.). (emphasis added).

- *Partial structure:* Tamsulosin hydrochloride is a hydrochloride salt of tamsulosin or ((R)-5-(2-(2-(2-ethoxyphenoxy)ethylamino)propyl hydrochloride and applicant claims an amorphous form. Applicant discloses physical and chemical properties describing the amorphous form such as a DSC thermogram, melting point, and an x-ray diffraction pattern but the applicant only claims a subset of these defining properties to define the amorphous form. Hancock and Zografi, 1997 notes that absence of x-ray diffraction peaks is strong evidence for an amorphous form but also notes that spectroscopy and thermoanalytical methods are used as support for an amorphous form (page 5, column 2 to page 7, column 1). In claiming of subset of the disclosed parameters, applicant only does not completely identify the amorphous form.
- *Physical and/or chemical properties*: The disclosure provides DSC thermogram, IR spectrum, and X-ray diffraction profiles of the compound. Though the applicant discloses a description of amorphous tamsulosin hydrochloride, the applicant has not claimed these properties as taught in the specification. The claims independently recite a partial combination of the physical and chemical properties which identify the amorphous form. In claiming a subset of properties it becomes unclear which properties are crucial to define the amorphous structure such that one of skill in the art would know they were in possession of it. Is the DSC thermogram more important than melting point? Which physical and chemical properties are required to properly define and be in possession of this amorphous form? As the applicant discloses these physical and chemical properties, the melting point, DSC thermogram, and x-ray diffractogram, to define the amorphous form, the claims are not commensurate in scope with the disclosed amorphous form.
- *Functional characteristics:* The applicant acknowledges that a preferred method for distinguishing an amorphous form is characterized on the basis of the absence of diffraction at all angles in an x-ray powder diffractogram. Brittain, 1999 teaches that an X-ray diffraction will be dependent on the wavelength of the incident beam and the

spacing between planes (i.e. d-spacings) (Brittain, 1999) and in essence the claimed pattern could change when using a different wavelength of radiation, and thus the x-ray diffraction pattern is not adequately described to show possession of an amorphous form of tamsulosin hydrochloride. The specification further discloses the prepared amorphous form of tamsulosin hydrochloride can be characterized by the following physico-chemical methods: differential scanning calorimetry, melting point determination, IR spectroscopy, and X-ray powder diffraction. Since x-ray diffraction is a standard method of determining order in a system, x-ray diffraction may be used to imply that since there is no order in the system, it is implied only disorder is present in the system (Hancock and Zografi, 1997; page 5, column 2). Hancock and Zografi, 1997 also teaches that viscosity is the most characteristic property in the amorphous state and teaches molecular probes, spectroscopy, and thermal analysis has been used to describe amorphous forms (page 6, columns 2 and 3). There are no identifying functions associated with the amorphous form of tamsulosin hydrochloride, only a subset of physical and/or chemical properties of an amorphous form claimed. Thus the applicant has not provided a claim which describes the amorphous form with the complete set of evidence required to put one in possession of the claimed invention.

- Method of making the claimed invention: The applicant describes an amorphous form characterized by describing a melting point, an IR band, or absence of X-ray peaks. The method to describe the amorphous form in the claims is broad and overlaps with a larger genus by claiming an amorphous form with one IR band, DSC thermogram described by one peak, or an X-ray diffractogram free of discrete peaks without providing the x-ray diffractogram and the wavelength of radiation used in the x-ray diffraction. The claims recite only an amorphous form defined by a subset of the physical and chemical characteristics which are disclosed to completely describe the amorphous form but do not claim the complete set of characteristics required to describe tamsulosin hydrochloride, thus encompassing a genus of amorphous forms that is not adequately described or supported.

- The possible number of ways to claim an amorphous compound as described by a DSC thermogram, IR spectrum, and X-ray diffraction profile are limitless. Although the

claims may recite some physical and chemical characteristics, the claims lack written description because there is no correlation between physical and chemical properties of the compounds as claimed. While the specification describes an amorphous form that is completely characterized by a melting point, an IR spectrum, a DSC thermogram, and the absence of x-ray diffraction peaks, the scope of the claims are greater than supported in the specification as the claims only partly described these characteristics by claiming only a melting point, an IR band, or the absence of x-ray diffraction peaks. Thus the scope of compounds in the claims is greater than the scope of compounds disclosed in the specification and neither the claims nor the specification completely describe the amorphous tamsulosin hydrochloride compounds encompassed by the claims. As such the claims are not commensurate in scope with the amorphous tamsulosin hydrochloride identified in the specification tables and/or examples. The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 to 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyazawa et al, 2001 (*Current Therapeutic Research* Vol. 62(9), provided in the 05/05/2009 restriction requirement), in view of US Patent 6,395,300 (Publication date: 05/28/2002; provided in the 05/05/2009 restriction requirement), hereafter referred to as the '300 patent.

Applicant claims an amorphous form of tamsulosin hydrochloride and further defines properties of the compound (i.e. DSC thermogram, IR spectrum, X-ray powder diffraction).

Determination of the scope and content of the prior art - (MPEP 2141.01)

Miyazawa et al, 2001 teaches tamsulosin hydrochloride is a potent α1-adrenergic receptor agonist for therapeutic use in benign prostatic hyperplasia (page 604, paragraph 1, lines 1-5).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The prior art teachings of Miyazawa et al, 2001 differ from the claimed invention as follows: Miyazawa et al, 2001 does not disclose an amorphous form of tamsulosin hydrochloride. However, the '300 patent teaches all the limitations that are deficient in Miyazawa et al, 2001: The '300 patent discloses a method for producing drugs in a crystalline state, an amorphous state, or mixtures thereof depending on how droplets are dried and the excipients present (column 12, lines 42-45) wherein the preferred drugs include tamsulosin hydrochloride (column 7, lines 45-64).

Per MPEP § 2141 and KSR as discussed *supra*, by employing the rationale in (C) above, it would be obvious for one of ordinary skill in the art to attempt use a process of improving dissolution on any of the preferred drugs, including tamsulosin hydrochloride, as the process in the '300 patent provides a method to overcome a rate-limiting step to attain therapeutically effective drug doses (column 1, lines 17-19). The success in processing these therapeutic agents provides one of ordinary skill with a reasonable expectation for success. Also, the number of "identified, predictable solutions" would be any preferred drug which would all be "obvious to try" in the method claimed in the instant application. Thus, it would have been *prima facie* obvious at the time the invention was made for one of ordinary skill in the art to use a process to improve the dissolution of a preferred drug ('300, column 7, line 45 to column 8, line 9).

The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. In the instant application the applicant claims profiles of the compound using DSC thermogram, IR spectrum, X-ray powder diffraction. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

Finding of prima facie obviousness - Rational and Motivation - (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the tamsulosin hydrochloride of Miyazawa et al, 2001 with process to produce an amorphous form as taught in the '300 patent.

One of ordinary skill in the art would have been motivated to do this because the '300 patent provides a method which enhances the dissolution rate of low solubility drugs in aqueous biological fluids (column 3, lines 41-46) and provides a method to overcome a rate-limiting step to attain therapeutically effective drug doses ('300, column 1, lines 11-14 and column 1, lines 17-19). In light of the forgoing discussion, the

Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed; all claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND P. YEAGER whose telephone number is (571) 270-7681. The examiner can normally be reached on Mon - Thurs 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.P.Y.

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